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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,111	06/20/2003	Lucina Galina-Pantoja	P05551US01	7776

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DES MOINES, IA 50309-2721

EXAMINER

NOBLE, MARCIA STEPHENS

ART UNIT PAPER NUMBER

1632

DATE MAILED: 08/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/600,111

Applicant(s)

GALINA-PANTOJA ET AL.

Examiner

Marcia S. Noble

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 2, 18, 32 and 46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2, 18, 32 and 46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Status of Claims***

1. In Applicant's Response to the non-final rejection, filed 6/13/2006, claims 9, 25, 39, and 53 are cancelled and claims 2, 18, 32, and 46 have been amended. Claims 2, 18, 32, and 46 are under consideration.

### ***Priority***

2. Applicant previously claims priority to provisional application No. 60/370,725, which failed to provide any description of the instant invention. Applicant amended the specification to recite provisional application 60/390,725, filed 6/21/2002, which does disclose the instant invention. Therefore benefit of priority of the earlier filing date is granted.

### ***Specification***

3. The use of trademarks LSM<sup>®</sup> (p. 7, line 26), Pfizerpen<sup>®</sup> G (p. 12, line 20), Garacin<sup>®</sup> (p. 12, line 20), Suvaxyn<sup>®</sup> (p. 12, line 33), Respinfend<sup>®</sup> (p. 12, line 33), and Neo-Terramycin<sup>®</sup> (p. 14, line 14) has been noted in this application.

Applicant amendment to trademarks in the specification and efforts to prevent improper use of trademarks is acknowledged.

### ***Information Disclosure Statement***

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4. The listing of references in the specification is not a proper information disclosure statement. Applicant acknowledgement this statements in their response is noted and made of record.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 2, 18, 32, and 46, stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for measuring and predicting lifetime average daily gain (ADG) among two or more pigs comprising providing two or more pigs, determining in each pig the quantity of CD16/CD2 double-staining positive antigen-expressing PBMC cells, determining a statistically significant association between an pig's quantity of CD16/CD2 double-staining antigen-expressing PBMC cells and AGD, does not reasonably provide enablement for above described method as a method for selecting for robustness or for the measurement of CD16/CD2 quantity in any cells and also does not enable the use of this method for selecting for the pig in order to improve robustness based on association. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

Claims 9, 25, 39, and 53 are canceled, therefore rendering their rejection moot.

Applicant traverse this rejection on the grounds that the Office Action failed to meet the initial burden of establishing an explanation to doubt the scope of enablement of the claimed invention. Applicant argues that even if the specification does not disclose the actual selection of pigs for robustness based on the data for robustness selection, it is not synonymous with one skilled in the art being unable to do so. Applicant further explains that the specification provides for a specific assay of PBMC cells for CD2 and CD16 stained cells and provides a method of correlating CD2/CD16 positive PBMC cell with average daily gain. Applicant's further explain that one skilled in the art can use this data to identify and select for robust pigs for use in breeding or other production systems. Applicant states that Examiner has failed to provide any reason to doubt that one of skill in the art would not be able to select a pig with robustness based on lifetime average daily gain, hot carcass measurements, or feed conversion.

These arguments are not found persuasive because as mentioned before, the breadth of the instant invention goes beyond intended use of the claimed method and encompasses aspects such as selective breeding schemes that are not enabled by the specification. As previously stated in the previous action, ". In the livestock production art, "selection" encompasses a breeding strategy and system and short and long-term impacts to affect such a breeding plan. The instant specification does not disclose the use of the instant methods to develop, implement, and analyze breeding based on the relationship between CD16/CD2 PBMC cells. [p. 6, last par]". This was not a statement of doubt of the facts of the specification or instant invention. The invention disclosed by

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the specification provides a potentially powerful tool for doing this type of selection or determination for robustness. However, although a selection/breeding program is still encompassed by the claims, there is no specific guidance to demonstrate how this method functions in a selection program with all the multiple facets that can affect such a selection program. The instant method demonstrates a correlation between CD2/CD16 PMBC cells and pig average lifetime daily gain. Although a powerful tool for predicting robustness, the method does not and can not produce a causal relationship between CD2/CD16 positive cells and average gain of a pig. As previously stated in the action, other factors such as heat stress, ailments, injury, etc... can mask or negate the above observed relationship. The specification does not provide means of using the instant tool in a selection wherein it overcomes these extenuating circumstances that are commonly present in selection processes in a production system. Therefore, the specification is not enabled for such types of selections or determinations. Furthermore, it must be noted that the amendment to the claims to recite "determine", more strongly encompasses the causative relationship between CD2/CD16 positive PBMC cells and average daily gain, which is improper. Again, the correlative nature of the instant method is enabling for a predictive method and identifying potential in pigs. It does not allow for the full scope of the invention which also encompasses selection in pig production.

It is also noted that the scope of the rejection was also limited to cd2/CD16 positive PBMC cells. The specification only discloses the isolation of these cells and the correlation with cd2/CD16 positive PBMC and average gain. The specification does not

provide for any CD2/CD16 positive cells have a correlation with average gain as claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 2, 18, 32, and 46 ~~stand~~ rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 9, 25, 39, and 53 are canceled, therefore rendering their rejection moot.

The instant claims recite, "selecting" or "selection". The metes and bounds of this term is unclear by its uses in the claims and specification. Selection may be defined as sorting in the instant invention or could have broader implications in the driving a genetic change for improvement of livestock product. It seems that both may be implied in the instant invention, but to what extent is not clear.

Applicant amended the claims to read "determine" as well as "selecting" in the instant method. Therefore, the instant method still is indefinite for the reasons previously mention and restated above. The rejection stands.

7. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marcia S. Noble whose telephone number is (571) 272-5545. The examiner can normally be reached on M-F 9 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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